Initial Approval: October 9, 2013

Revised Date: July 8, 2015

CRITERIA FOR PRIOR AUTHORIZATION

Herceptin® (trastuzumab)

PROVIDER GROUP Pharmacy

Professional

MANUAL GUIDELINES The following drug requires prior authorization:

Trastuzumab (Herceptin)

CRITERIA FOR METASTATIC GASTRIC CANCER Must meet all of the following:

- Patient must have a diagnosis of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma
- · Patient must have not received prior treatment for metastatic disease
- Patient must be receiving trastuzumab in combination with cisplatin and either capecitabine or 5flurouracil
- Patient must be 18 years of age or older
- Patient must not be pregnant

CRITERIA FOR ADJUVANT BREAST CANCER Must meet all of the following:

- Patient must have a diagnosis of HER2 overexpressing breast cancer
- Patient must have one of the following:
 - Node-positive disease
 - Node-negative disease and one of the following:
 - ER/PR-negative
 - Tumor size >2cm
 - Age < 35 years of age
 - Histological and/or nuclear Grade 2 or 3
- Patient must be receiving one of the following regimens:
 - Trastuzumab in combination with doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - o Trastuzumab in combination with docetaxel and carboplatin
 - o Trastuzumab as a single agent following multi-modality anthracycline based therapy
- Patient must be 18 years of age or older
- Patient must not be pregnant
- Patient must not be receiving trastuzumab for more than 12 months

PA Criteria

CRITERIA FOR METASTATIC BREAST CANCER Must meet all of the following:

- Patient must have a diagnosis of HER2 overexpressing metastatic breast cancer
- Must be used in combination with paclitaxel in patients who have not received prior treatment for metastatic disease
- May be used as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease
- Patient must be 18 years of age or older
- Patient must not be pregnant

LENGTH OF APPROVAL: 12 months